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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,132	05/29/2001	Knut E. Rasmussen	01-11 US	9635

7590

08/13/2002

Varian Inc
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EXAMINER

PADMANABHAN, KARTIC

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 08/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/857,132

Applicant(s)

RASMUSSEN ET AL.

Examiner

Kartic Padmanabhan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.
3. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. *Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading.* If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables

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having more than 50 pages of text are permitted to be submitted on compact discs.) or

REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a).

"Microfiche Appendices" were accepted by the Office until March 1, 2001.)

(e) BACKGROUND OF THE INVENTION.

(1) Field of the Invention.

(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(f) BRIEF SUMMARY OF THE INVENTION.

(g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).

(h) DETAILED DESCRIPTION OF THE INVENTION.

(i) CLAIM OR CLAIMS (commencing on a separate sheet).

(j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

(k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 1 is rejected as vague and indefinite for the recitation of a volume V_a because it is unclear if the container has this volume or if the acceptor solution in the container has this volume. In addition, it is unclear if " $V_s:V_a$ " is a ratio or not, as applicant has not recited it as such. This notation could also mean " $V_s=V_a$ ". Applicant should insert "An" at the beginning of the claim. Applicant should also change "characterised" and "analysed" to conform to US spelling. In addition, "characterised in" in line 2 has spaces between the letters, which needs to be fixed.

7. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are the way in which the second container is "arranged" in the first container.

8. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely

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exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation a first container, and the claim also recites a disposable container, which is the narrower statement of the range/limitation.

9. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation stirring means, and the claim also recites a magnetic bar, which is the narrower statement of the range/limitation.

10. In claims 2 and 3, applicant should insert "The" at the beginning of the claim. In addition, applicant should remove the spaces between the letters of "characterised in", while also changing "characterised" and "fibre" to conform to US spelling in both claims.

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11. In claim 2, applicant should insert “claim” before the number 1 in the first line of the claim.

12. Claim 3 is rejected as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). For purposes of this office action, the claim is being treated as being dependent on claim 1.

13. Claim 3 is rejected as vague and indefinite for the recitation of “the container”. Since there are multiple containers, it is unclear to which container applicant is referring. In addition, the intended meaning of the term “active polymer” is unclear, thereby also rendering the claim vague and indefinite.

14. Claim 4 recites the limitation "the use" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim. In addition, applicant should remove the spaces between the letters of “characterised in”, while also changing “characterised” to conform to US spelling. Further, the recitation of “the membrane wall is impregnated” is vague and indefinite because claim 1, on which claim 4 depends, refers to multiple walls, so it is unclear to which wall applicant is referring. Also, the term “enriched analyte” in step d renders the claim vague and indefinite because applicant has not recited anywhere in the process how the analyte becomes enriched.

15. Claim 5 recites the limitation "the use" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim. In addition, applicant should remove the spaces between the letters of “characterised in”, while also changing “characterised”, “immobilisation”, and “immobilised” to conform to US spelling. The term “thereof” in step b is vague and indefinite because it is unclear, with the present terminology, what the container is filled with.

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Further, the recitation of “immobilised liquid” is vague and indefinite because there is no positive recitation of a step in which liquid is immobilized. The phrase “for immobilisation” is only an intended use and does not satisfy this requirement. Also, the term “enriched analyte” in step d renders the claim vague and indefinite because applicant has not recited anywhere in the process how the analyte becomes enriched.

16. In claims 6-10, applicant should replace “A” at the beginning of the claim with “The”.

17. Claim 6 is rejected as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). For purposes of this office action, the claim is being treated as being dependent on claim 4. In addition, applicant should remove the spaces between the letters of “characterised in”, while also changing “characterised” and “fibre” to conform to US spelling.

18. In claim 7, applicant should remove the spaces between the letters of “characterised in”, while also changing “characterised” and “fibre” to conform to US spelling. In addition, the intended meaning of the term “active polymer” is unclear, thereby also rendering the claim vague and indefinite.

19. Claim 8 is rejected as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). For purposes of this office action, the claim is being treated as being dependent on claim 5. In addition, applicant should remove the spaces between the letters of “characterised in”, while also changing “characterised” to conform to US spelling.

20. Claim 9 is rejected as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). For purposes of this office

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action, the claim is being treated as being dependent on claim 5. In addition, applicant should remove the spaces between the letters of “characterised in”, while also changing “characterised” and “immobilised” to conform to US spelling. In addition, the claim is rejected as vague and indefinite for the recitation of “liquid immobilised in the membrane” because there is no positive recitation of this step in this claim or on any claim on which claim 9 depends.

21. Claim 10 is rejected as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). For purposes of this office action, the claim is being treated as being dependent on claim 5. In addition, applicant should remove the spaces between the letters of “characterised in”, while also changing “characterised” to conform to US spelling. Further, the two recitations of “basic” render the claim vague and indefinite because it is unclear if applicant is referring to pH or not. Applicant may wish to consider using the term “alkaline”.

22. Claim 11 recites the limitation “the form” in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim. In addition, applicant should remove the spaces between the letters of “characterised in”, while also changing “characterised” and “immobilised” to conform to US spelling. Further, the recitation of having the form of a sponge is vague and indefinite because a sponge will take the form of the container into which it is inserted.

Claim Rejections - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

24. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

25. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

26. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rasmussen et al. (WO 97/25606) in view of Berg (US Pat. 6,164,144).

Rasmussen et al. teach a device and method for liquid-liquid microextraction. The method comprises providing a carrier, modifying the carrier, immobilizing a solvent (acceptor solution) on the carrier surface, contacting the carrier with the sample (which may be in solution), concentrating and fixing the analyte of interest to the solvent, and analyzing the carrier. Preferably, a carrier is used as the fiber. The fibers for use with the invention may be made of porous polymers such as polyacrylate. The amount of solvent to be immobilized on the solvent is in the range of 1-5 ul (page 4). The carrier with immobilized solvent is inserted into

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the sample solution, where the pH may be altered to favor partitioning of analyte and solvent (page 5). In one embodiment, the fiber is withdrawn into the needle of a syringe, and the needle is used to penetrate the septum of a solvent vial, at which time the fiber is lowered and solvent is immobilized. The fiber is then withdrawn back into the needle and used to penetrate the sample vial. After the fiber is lowered into the vial, analytes are partitioned by agitating the vial (page 7). Since the fiber only accommodates 1-5 ul of sample, it is inherent that the sample vial has a volume greater than 50X this amount. The sample solution for use with the invention may be plasma. However, the reference does not specifically teach the use of a hollow fiber, magnetic stirring bar, an acidified acceptor solution, or a sponge.

Berg teaches methods and device for solid phase microextraction (SPME). The reference discloses the use of a fiber with SPME, wherein the fiber acts as a "sponge". In addition, the reference also teaches the use of a magnetic stirring bar as the means of agitation of a sample in a vial.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use a magnetic stirring bar, a hollow fiber, and an acidified acceptor solution with the invention of Rasmussen et al. By using a hollow fiber, one would have been able to fill the fiber with acceptor solution rather than immobilizing the solution on the surface of the fiber. With such an arrangement, partitioning will occur between analyte and acceptor within the fiber, at which time acceptor solution with analyte can be removed and analyzed. One would have been able to use this arrangement with a reasonable expectation that it would provide results similar to those when acceptor is immobilized on the surface of the fiber. It would have further been obvious to use a magnetic bar as the stirring means to establish extraction equilibrium

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(partitioning between sample and acceptor) for the analyte because magnetic stirring bars are very well known in the art for use when agitation is necessary, as taught by Berg et al. One would have had a reasonable expectation of success in using a stirring bar as the agitation means with the method of Rasmussen et al. because both Berg and Rasmussen et al. are drawn to extraction methods and one would have recognized that any agitation means could have been used with the method and device of Rasmussen et al. Furthermore, it would have been obvious to acidify the acceptor solution of Rasmussen et al. because Diazepam, the analyte of interest in Example 1, has its highest partition coefficient at an acidic pH. Finally, it would have also been obvious to modify the method and device of Rasmussen et al. by using a sponge instead of a fiber as the disposable container. Since Berg teaches that the fiber of the method acts as a sponge, one would have had a reasonable expectation of success in carrying out the method of Rasmussen et al. with the replacement of the fiber with a sponge material. In addition, although Berg deals with solid phase microextraction, the teaching of Berg would have been applicable to the modified method of Rasmussen et al. because Rasmussen et al. use a SPME fiber in their liquid-liquid microextraction method (page 10).

Conclusion

Claims 1-11 are rejected.

References: Pawliszyn, Kilambi et al., Kim et al., Utzinger, Cussler et al., and Verachtert are cited as art of interest for teaching various extraction devices and methods.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 703-305-0509. The examiner can normally be reached on M-F (8:30-5:00).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-5207 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kartic Padmanabhan
Patent Examiner
Art Unit 1641


August 12, 2002



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800/641